IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE BENICAR (OLMESARTAN) PRODUCTS LIABILITY LITIGATION	**MDL No. 2606** Master Case No. 15-2606 (RBK/JS) Hon. Robert B. Kugler, U.S.D.J. Hon. Joel Schneider, U.S.M.J.
THIS DOCUMENT RELATES TO ALL CASES	

DEFENDANTS' BRIEF IN OPPOSITION TO PLAINTIFFS' *DAUBERT* MOTION TO EXCLUDE TESTIMONY OF KEITH WILSON, M.D.

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INTRODUCTION

Plaintiffs' primary criticism of gastroenterologist Dr. Keith Wilson's opinions is that he respected the limits of existing peer-reviewed data and considered that data through the lens of the traditional hierarchy of scientific evidence. But that critique goes to the weight of Dr. Wilson's opinions and is not a proper basis for precluding them. Dr. Wilson conducted a thorough review of substantially the same peer-reviewed data as considered by plaintiffs' experts, but could not identify reliable scientific evidence to support an opinion that olmesartan can cause sprue-like enteropathy. His opinions are grounded in the "sufficient facts and data" required by Rule 702. Contrary to plaintiffs' contention, his unwillingness to make the same unsupported leaps from existing evidence that plaintiffs' experts have made is not a methodological flaw. Rather, it is a scientific virtue. His opinions should not be excluded simply because plaintiffs disagree with them.

LEGAL ARGUMENT

I. Dr. Wilson is qualified and His Opinions Grow Out Of His Research and Experience Outside of this Litigation.

Dr. Wilson has precisely the sort of "knowledge, skill, training, education, [and] experience [necessary] to testify with authority on the" existing science concerning olmesartan and render opinions concerning reasonable conclusions that can be drawn from that science. *Yarchak v. Trek Bicycle Corp.*, 208 F. Supp. 2d

470, 494-95 (D.N.J. 2002). Moreover, Dr. Wilson's opinions "grow[] naturally and directly out of research [he] has conducted independent of the litigation." *Magistrini v. One Hour Martinizing Dry Cleaning*, 180 F. Supp. 2d 584, 594 (D.N.J. 2002). As the Court reckoned, "in this kind of case it seems to me that the qualifications are not going to be an issue." *In re Benicar (Olmesartan) Prods. Liab. Litig.*, Jan. 25, 2017 Transcript at 29:7-10 (Certification of Daniel B. Carroll, Esq. ("Carroll Cert.") Ex. A). Plaintiffs' protest to the contrary (*see* Plaintiffs' Motion to Exclude Keith Wilson, M.D. ("Wilson Motion") at 3-4, 19 (Dkt. 1077-1)) is specious.

Dr. Wilson has been a board-certified gastroenterologist for nearly a quarter-century and holds an endowed chair in the Division of Gastroenterology, Hepatology and Nutrition in the Department of Medicine at Vanderbilt University. *See* Wilson Report at 15 (Plaintiffs' Certification in Support of Motion to Exclude Dr. Wilson ("Pls.' Wilson Cert.") Ex. 2). He serves at the head of an internationally-recognized research program whose purpose is to study gastrointestinal immunology and inflammation. *See id.* He is an associate editor of *Gastroenterology*, recognized as the premier journal in this area of medicine. *See id.* at 16. Dr. Wilson has served as a panelist on dozens of National Institutes of Health grant reviews concerning gastrointestinal issues. *See id.* And he has vast clinical experience, routinely caring for "all types of patients including many with

acute and chronic diarrhea, inflammatory bowel disease, celiac disease, and various enteropathies." *See id.* at 16-18. If plaintiffs believe that Dr. Wilson's academic focus makes him less credible (*see* Wilson Motion at 4 (Dkt. 1077-1)), that is an issue to be determined by a jury and not a basis for disqualifying Dr. Wilson. *See, e.g., Kannankeril v. Terminix Int'l, Inc.*, 128 F.3d 802, 806 (3d Cir. 1997) ("credibility decisions arise after admissibility has been determined").

That Dr. Wilson "had no knowledge or experience regarding OIE until he was hired as a defense expert" (Wilson Motion at 19 (Dkt. 1077-1) speaks more to the quantum and quality of the science supporting these cases than it does Dr. Wilson's qualifications and methods. Indeed, plaintiffs' expert Dr. Susan Huftless also had never encountered olmesartan and sprue-like enteropathy before her retention in this litigation. *See, e.g.,* Huftless Dep. at 89:24-90:7 (Carroll Cert. Ex. B). Plaintiffs' criticism is rooted in the supposition that there is a "scientific consensus" that "OIE" is a real condition, substantiated through meaningful scientific data. Wilson Motion at 3 (Dkt. 1077-1). As demonstrated in other papers submitted to this Court, however, that supposition is not supported. *See, e.g.,* Brief in Support of Motion to Exclude Testimony of Dr. Leffler and Dr. Benjamin Lebwohl at 15-25 (discussing studies) (Dkt. 1066-1).

Even though Dr. Wilson had not had direct experience before this litigation with what plaintiffs term "OIE," his opinions nonetheless grow from his

substantial work outside of this litigation concerning gastrointestinal disease and injury. *See* Wilson Rep. at 15-16 (Pls.' Wilson Cert. Ex. 2) (summarizing a vast record of research relating to "etiological aspects of gastrointestinal inflammation and injury," such as alleged in this litigation). Courts in this Circuit "have eschewed imposing overly rigorous requirements of expertise and have been satisfied with more generalized qualifications." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 741 (3d Cir. 1994), and indeed this Court admonished the parties not to file as here *pro forma* motions challenging the qualifications of experts. Dr. Wilson's experience makes him well-situated to conduct the scientific assessment in which he engaged and render the opinions proffered, wherever those opinions may sit relative to the "scientific consensus" that plaintiffs pretend exists.

II. Dr. Wilson's Opinions Are Well-Grounded.

Dr. Wilson formed his opinions that the existing science does not support a causal nexus between olmesartan and sprue-like enteropathy through a critical assessment of the available data. *See generally* Wilson Rep. (Pls.' Wilson Cert. Ex. 2); Wilson Dep. at 98:9-22 (focus was on "how good is the evidence" available) (Carroll Cert. Ex. C). Courts in this Circuit and the Reference Manual on Scientific Evidence, among others, recognize that all data are not created equal. *See, e.g., Soldo v. Sandoz Pharms. Corp.*, 244 F. Supp. 2d 434, 457-58, 532-44 (W.D. Pa. 2003) (delineating between the quality of case reports versus

epidemiology for proof of causation); FJC, Reference Manual on Scientific Evidence at 723-24 (3d ed. 2011) (describing the hierarchy of medical evidence). So too did Dr. Wilson, and his unwillingness to stretch data beyond their appropriate limits is not a reason to exclude his opinions. Dr. Wilson's opinions are rooted in "'good grounds,' based on what is known," and should be admitted. *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 590 (1993).

A. Dr. Wilson's Evaluation of Data Was Reliable.

Dr. Wilson reviewed substantially the same peer-reviewed publications relating to olmesartan that plaintiffs' experts did, and found that existing science fails to prove olmesartan causes sprue-like enteropathy. *See generally* Wilson Rep. (Pls.' Wilson Cert. Ex. 2). Dr. Wilson did not "willfully ignore[] or unreasonably downgrade[]" the evidence that plaintiffs find compelling (Wilson Motion at 20 (Dkt. 1077-1)); rather, he gave the available data its due and evaluated the data against generally-accepted criteria for assessing general causation. *See generally* Wilson Rep. (Pls.' Wilson Cert. Ex. 2). Unlike plaintiffs' experts, however, he gave the available data *only* its due. Dr. Wilson's opinions are based in the reliable methodology called for by Rule 702 and *Daubert*.

The ability to make evidence-based determinations relating to causation depends on "how good" the science supporting the proposition is. Wilson Dep. at 98:9-22 (Carroll Cert. Ex. C); *accord In re Propulsid Prods. Liab. Litig.*, 261 F.

Supp. 2d 603, 615 (E.D. La. 2003) (judicial proceedings "must function in the present assessing evidence that presently exists"). Dr. Wilson employed a recognized and sophisticated method for evaluating the available data. Wilson Rep. at 1-8 (describing and applying the grading system based on the well-known and recognized hierarchy of scientific evidence) (Pls.' Wilson Cert. Ex. 2). A lower grade did not render the data a nullity; it reduced the weight of the data relative to data of a higher grade. *See id.* At its base, the grading system employed by Dr. Wilson is essentially the same as the hierarchy of scientific evidence recognized in the Reference Manual for Scientific Evidence. *Compare id.* at 2 (identifying the grades) *with* FJC, Reference Manual on Scientific Evidence at 723-24 (3d ed. 2011) (describing the hierarchy of medical evidence). After assessing the available peer-reviewed literature, Dr. Wilson considered the evidence in light of the Bradford-Hill criteria. *See id.* at 10-12. Application of the Bradford-Hill criteria has long been accepted as a reliable method upon which to render general causation opinions. *See, e.g., In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, Nos. 11-5304 & 08-08, 2013 WL 1558690, at *3 (D.N.J. Apr. 10, 2013) ("the Bradford Hill criteria are 'broadly accepted' in the scientific community for 'evaluating causation'") (internal citations omitted). This "Wilson test," as plaintiffs call it (Wilson Motion at 13-15 (Dkt. 1077-1)), is not methodologically flawed.

Nor were Dr. Wilson's methods "directed" by defense counsel, which plaintiffs claim on the picayune basis that Dr. Wilson does not refer to the Bradford-Hill criteria as "the Bradford-Hill criteria" in practice. *Id.* at 5, 20-21. Whether or not Dr. Wilson knows those criteria as "the Bradford-Hill criteria," Dr. Wilson uses them every day in evaluating relationships between drugs and reported effects. Wilson Dep. at 279:18-289:21 (Carroll Cert. Ex. C). He teaches them to students. *See id.* at 295:11-17. And, unlike plaintiffs' experts, each criterion was important to his evaluation of causation. *Compare, e.g.,* Wilson Rep. at 10-12 (considering all nine criteria) (Pls.' Wilson Cert. Ex. 2) *with* Lebwohl Rep. at 28-29 (identifying five of the nine criteria for consideration) (Defendants' Certification in Support of Motion for Summary Judgment (Dfs.' SJ Cert."), Ex. D) *and* Leffler Rep. at 11 (identifying criteria for consideration, some of which are grounded in the Bradford-Hill criteria) (Dfs.' SJ Cert. Ex. A).

In any event, plaintiffs take particular issue with Dr. Wilson's characterization of data from three of the sources he assessed: (a) the ROADMAP study (*see* Wilson Motion at 10-11, 21-22, 24 (Dkt. 1077-1)), (b) the Basson study (*see id.* at 11-12, 21-22), and (c) published case reports (*see id.* at 14-15, 22-24). As set forth below, his assessment of these data was methodologically sound.

The ROADMAP Study. The ROADMAP study was the largest randomized olmesartan trial. *See* J. Menne et al., "Olmesartan and Intestinal Adverse Effects in

the ROADMAP Study," *Mayo Clin. Proc.* at 1230-1232 (December 2012)) ("Menne paper") (Defendants' Certification in Support of Motion to Exclude Susan Hutfless Ph.D. ("Dfs.' Hutfless Cert.") Ex. Y). The study collected data on gastrointestinal effects experienced by participants, but gastrointestinal effects were not a primary end point for the study. *See id.* Dr. Wilson recognized that limitation, and "downgraded" the value of the ROADMAP study data accordingly. Wilson Rep. at 6 (Pls.' Wilson Cert. Ex. 2). Plaintiffs complain that Dr. Wilson did not go far enough, claiming that the data concerning gastrointestinal effects are invalid simply because those effects were not a primary end point of the study. *See* Wilson Motion at 10 (Dkt. 1077-1). There is no support for this assertion. Indeed, the gastrointestinal effects data collected in the ROADMAP study were published in a peer-reviewed journal. Menne paper (Dfs.' Hutfless Cert. Ex. Y).

Dr. Wilson's treatment of the ROADMAP study data as more valuable than data from case reports is entirely consistent with the hierarchy of scientific evidence. *See* FJC, Reference Manual on Scientific Evidence at 723-24 (3d ed. 2011) (describing the hierarchy of medical evidence). *See* Wilson Motion at 10-11 (Dkt. 1077-1). The ROADMAP study involved high-dose olmesartan, once daily in 2232 people treated for a median of 3.2 years. *See* Menne paper (Dfs.' Hutfless Cert. Ex. Y). To put case reports ahead of statistical findings would turn the hierarchy of scientific evidence on its head. *Accord* Wilson Dep. at 192:10-24 ("I

don't think one patient is worth trying to make any conclusions about causation from") (Carroll Cert. Ex. C). That is the method pushed by plaintiffs' experts, and is one that should not be endorsed by the Court. *See, e.g., Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1316 (11th Cir. 1999) ("While we acknowledge the importance of anecdotal studies for raising questions and comparing clinicians' findings, in the face of controlled, population-based epidemiological studies which find otherwise, these case reports pale in comparison"); *see also* Brief in Support of Motion to Exclude Testimony of Dr. Leffler and Dr. Benjamin Lebwohl at 34-40 (discussing methodological flaw of elevating case reports over more reliable data)(Dkt. 1066-1).

The Basson Study. The authors of the Basson study noted several limitations to their findings, and Dr. Wilson accounted for those limitations. *Compare* M. Basson et al., "Severe intestinal malabsorption associated with olmesartan: a French nationwide observational cohort study," *Gut* at 1-6 (2015)(Dfs.' Hutfless Cert. Ex. V) *with* Wilson Rep. at 7 (Pls.' Wilson Cert. Ex. 2). That should be a virtue of Dr. Wilson's methods, not a demerit (*see* Wilson Motion at 11-12, 21-22 (Dkt. 1077-1). *Cf. McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1245 (11th Cir. 2005) (opinion inexpert where "[t]he medical articles do not support these conclusions" and "[s]peculation replaces science").

Of particular consequence to Dr. Wilson was that the study looked only at "administrative data" concerning hospitalization from a discharge diagnosis of malabsorption "and there was no comparison with actual chart review data." Pls.' Wilson Rep. at 7 (Wilson Cert. Ex. 2); *see also* Wilson Dep. at 220:6-14 (discussing limitations of the Basson study) (Carroll Cert. Ex. C). For that reason, Dr. Wilson graded the Basson study data on a par with other studies such as the ROADMAP study data. *See id.* Contrary to plaintiffs' contention (*see* Wilson Motion at 10-11 (Dkt. 1077-1), however, Dr. Wilson did not dismiss the study. In fact, he considered it of similar value to other available studies, and more valuable than some. *See, e.g.,* Wilson Rep. at 6-8 (discussing studies) (Pls.' Wilson Cert. Ex. 2). If plaintiffs disagree with Dr. Wilson's conclusions concerning the value of the Basson study data, that argument goes to the weight of his opinion and not admissibility. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) (the standard for admissibility centers "on principles and methodology, not on the conclusions that they generate").

Case Reports. Dr. Wilson recognized that case report data are less reliable than data from other publications, such as case control and randomized studies. *See* Wilson Rep. at 2-8 (grading case reports lower than other studies)(Pls.' Wilson Cert. Ex. 2); *accord*, *e.g., Brumbaugh v. Sandoz Pharm. Corp.*, 77 F. Supp. 2d 1153, 1156 (D. Mont. 1999) ("Neither case reports nor adverse drug reaction

reports contain scientific analysis with the safeguards of a controlled experiment"). Dr. Wilson acknowledged that a limited subset of case report data suggests an association between olmesartan and sprue-like enteropathy (or symptoms of sprue-like enteropathy). *See* Wilson Motion at 16-17 (Dkt. 1077-1) (noting those acknowledgements). But, as plaintiffs' expert Dr. Benjamin Lebwohl stated, scientists must be "mindful of the ever-present scientific practice to avoid confusing correlation with causation." Lebwohl Rep. at 29 (Defs.' Motion to Exclude Drs. Leffler and Lebwohl Ex. D); *accord, e.g., Henricksen v. ConocoPhillips Co.*, 605 F. Supp. 2d 1142, 1175 (D. Wash. 2009) ("an association does not equal causation, and it is the duty of scientists to rigorously analyze the data to determine whether or not an association is causal").

Dr. Wilson heeded that practice, and his unwillingness to leap from unreliable and incomplete data is good science. *Cf. McClain*, 401 F.3d at 1245 (unsupported extrapolation is inexpert). That some courts may find case reports probative of causation does not render Dr. Wilson's evaluation of the evidence methodologically unsound. Dr. Wilson did not "refus[e] to consider scientific evidence that does not involve a randomized controlled trial" (Wilson Motion at 23 (Dkt. 1077-1)), he simply gave that evidence less weight than other evidence.

Indeed, Dr. Wilson acknowledged the usefulness of less reliable data like case reports in clinical practice. *See, e.g.,* Wilson Dep. at 273:12-274:11 (would be

a "reasonable approach" to stop any medication that has been associated with gastrointestinal distress) (Carroll Cert. Ex. C). Dr. Wilson's opinion that the existing literature can guide clinical practice is not at odds with his opinion that the existing science does not support causation. *See* Wilson Motion at 17 (Dkt. 1077-1). It is merely a recognition that clinicians treat patients based on the information available, even if that information does not support a scientific conclusion that the treatment is needed. *Accord Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1205-07 (8th Cir. 2000) (delineating between inexpert opinion "concerned with identifying and treating [the plaintiff's] condition" and opinion seeking to "identify[] the specific substance that caused [the plaintiff's] condition").

* * *

It is of no moment that Dr. Wilson cannot identify a publication that concludes olmesartan does not cause sprue-like enteropathy. *See* Wilson Motion at 3 (Dkt. 1077-1). Dr. Wilson's opinion is that existing data does not support a causal nexus between olmesartan and sprue-like enteropathy, not that the existing data affirmatively demonstrates olmesartan does not cause sprue-like enteropathy. *See, e.g.,* Wilson Dep. at 110:7-118:19 (describing the inadequacy of existing studies, including studies by plaintiffs' experts, to support a general causation opinion) (Carroll Cert. Ex. C). And while Dr. Wilson cannot identify an article with *the exact words* "olmesartan does not cause sprue-like enteropathy" (the

question plaintiffs' counsel posed to him (Wilson Dep.at 124:5-15 (Carroll Cert. Ex. C)), he did find "multiple negative studies that . . . are higher level evidence that . . . found no association" between olmesartan and sprue-like enteropathy. *Id.* at 109:19-110:6; *see also* Wilson Rep. at 6-8 (describing those studies) (Pls.' Wilson Cert. Ex. 2). His opinion is predicated on reliable methodology, and should be admitted. *See* Fed. R. Evid. 702.

B. Dr. Wilson's Review of Data Was Adequate.

Dr. Wilson reviewed a broad swath of published, peer-reviewed data in forming his opinions. *See generally* Wilson Rep. (discussing case series, case reports, case control studies, randomized trials, and other studies)(Pls.' Wilson Cert. Ex. 2). Notwithstanding, plaintiffs argue that his opinions are not well-grounded because, they say, he neglected certain information. *See* Wilson Motion at 7-10, 22 (Dkt. 1077-1). But an expert need not review every piece of available information in order to render a reliable opinion. The Federal Rules require only that expert's opinions be "based on sufficient facts and data." Fed. R. Evid. 702(b). As set forth below, the information that Dr. Wilson did not review is not peer-reviewed, is not reliable evidence of causation, and therefore is not essential to a scientific review of the evidence. Dr. Wilson's review of the available data was adequate to support an admissible opinion.

Up to Date. Dr. Wilson reviewed Up to Date for information on work ups performed for acute and chronic diarrhea, not for the purposes of identifying peer-reviewed data concerning the effects of olmesartan. *Compare* Wilson Dep. at 35:7-36:13 (used Up to Date "as a way for me to organize my thoughts") (Carroll Cert. Ex. C) *with* Wilson Motion at 7-9 (failed to conduct a sound search for peer-reviewed information on Up to Date) (Dkt. 1077-1). Up to Date is a database of anecdotal clinical experiences, and in Dr. Wilson's estimation is not a source of reliable, peer-reviewed information. *See* Wilson Dep. at 32:15-33:16 (testifying that Up to Date is not peer-reviewed, that it is "somewhat reliable," and that he does not rely on it as a source of peer-reviewed information)(Carroll Cert. Ex. C).

Whatever his methods for searching the Up to Date database, Dr. Wilson reviewed substantially the same set of peer-reviewed data concerning olmesartan that plaintiffs' experts reviewed. *See supra* at 5. He received that information from places other than Up to Date. Plaintiffs' complaint about the reliability of Dr. Wilson's Up to Date search methodology (*see* Wilson Motion at 7-9 (Dkt. 1077-1)) is therefore inapposite.

Celiac Literature. Dr. Wilson did not conduct a thorough review of celiac literature because celiac disease is not at issue. Wilson Dep. at 102:7-16 (*See* Carroll Cert. Ex. C). Plaintiffs contend that celiac experience informs this litigation. *See* Wilson Motion at 9 (Dkt. 1077-1). But even if analogy between

celiac disease and what plaintiffs term "olmesartan enteropathy" were appropriate, the conditions are independent of one another. Plaintiffs' experts admit as much. *See, e.g.,* Leffler Rep. at 10 (identifying differences) (Dfs.' SJ Cert. Ex. A). Dr. Wilson's distinction between the two is a matter of evidentiary weight, not expert methodology. *See, e.g., Schwartz v. Avis Rent a Car Sys., LLC*, No. 11-4052, 2014 WL 4272018, at *5 (D.N.J. Aug. 28, 2014) (expert's election not to review data before a certain date "is only relevant to the weight of her testimony, not its admissibility") (Carroll Cert. Ex. E).

Internal Daiichi Sankyo Documents. Dr. Wilson did not review internal Daiichi Sankyo documents. *See* Carroll Cert. Ex. C (Wilson Dep.) at 208:4-17 ("I don't think that it's really relevant to the task that was put before me of assessing the medical literature"). That is not a methodological flaw, as plaintiffs contend. *See* Wilson Motion at 9-10 (Dkt. 1077-1). As Dr. Wilson testified, internal company documents are not peer-reviewed, and therefore do not reliably inform a conclusion on scientific causation. Wilson Dep. at 191:17-192:6 ("I don't know what internal drug company documents look like, but my supposition is, they don't reach the level of evidence of what I would expect from a peer-reviewed paper") (Carroll Cert. Ex. C). Indeed, as this Court has found, the internal documents on which plaintiffs have focused to support general causation do not provide such

proofs. *See In re Benicar (Olmesartan) Prods. Liab. Litig.*, No. 15-2606, 2016 WL 6652358 at *3-*8 (D.N.J. Nov. 8, 2016) (Carroll Cert. Ex. F).

Scientists need not review company documents to render informed and reliable opinions on causation. The election not to review those materials goes to weight of Dr. Wilson's opinions and not their admissibility. *See In re Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 427 (S.D.N.Y. 2016) ("Defendants' experts' failure to confront alleged conflicting statements made by Bayer does not warrant exclusion under *Daubert*"); *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 735 (S.D. W.Va. 2014) (expert's "failure to review particular [internal] documents" that purportedly "refute his conclusion" "goes to the weight of his opinion, not its admissibility").

FDA Pronouncements. Dr. Wilson did not give weight to the FDA's "conclusion" that olmesartan can cause sprue-like enteropathy, but this too is not a methodological flaw. *See* Wilson Motion at 12-13 (Dkt. 1077-1). The FDA was not purporting to make a scientific determination as to general causation. As set forth in defendant's motion to exclude plaintiffs' expert Dr. David Kessler, FDA pronouncements have a regulatory purpose that cannot be reliably translated to medical/scientific causation. *See* Memorandum in Support of Defendant's Motion to Exclude the Opinions of Dr. Kessler at 3-8 (Dkt. 1065-1).

* * *

Dr. Wilson assessed the peer-reviewed data relating to the issue at hand: whether the existing science supports the conclusion that olmesartan can cause sprue-like enteropathy. His opinions are not impaired because he did not review information that is not peer-reviewed or not relevant to the issue of medical causation. Dr. Wilson's opinions are "based on sufficient facts and data," and should be admitted. Fed. R. Evid. 702.

CONCLUSION

There are several common themes running through all of plaintiffs' motions to exclude Defendants' expert witnesses. First, they argue that there is a consensus that olmesartan causes sprue-like enteropathy, so that any defense expert who disagrees must be an outlier. Second, plaintiffs argue that there is no study that concludes that olmesartan does not cause sprue-like enteropathy, so olmesartan must cause it. Third, plaintiffs argue that if an expert has not published on sprue-like enteropathy that expert must be excluded -- but not plaintiffs' expert Dr. Susan Hutfless. Last, for plaintiffs, Dr. Joseph Murray, the lead author of the Mayo Clinic case series, is the foremost authority on sprue-like enteropathy, so there can be no disagreement with Dr. Murray – excepting, of course, plaintiffs' experts, who find Dr. Murray's clinical criteria of sprue-like enteropathy too restrictive, likely because it does not encompass every person who ever had a bellyache or diarrhea during the time they were treated with an olmesartan medicine for hypertension.

For the reasons set forth in Defendants' Opposition Briefs not one of these themes has any merit.

As to Dr. Wilson, specifically, Plaintiffs' Motion to Preclude his opinions (Dkt. 1077) should be denied for the reasons set forth above.

Respectfully submitted,

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